Zonghui Hu

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RESEARCH INTERESTS

Clinical trials, High dimensional data, Missing data and causal inference, Semiparametric models, Vaccine efficacy and design.

EDUCATION

Texas A& M University, College Station, TX

Ph.D., Statistics, 2004

M.S., Mathematics, 2000

RESEARCH EXPERIENCE

Mathematical Statistician

2004 to present

Biostatistics Research Branch,

National Institute of Allergy and Infectious Diseases

National Institutes of Health

Graduate Research Assistant

2000 to 2004

Department of Statistics & Large Animal Clinic,

Texas A& M University

Services

Associate Editor of Statistics in Medicine ICSA membership committee

2015 to present 2011 to 2013

REFEREED JOURNAL PUBLICATIONS As a statistical methodologist, I have first author publications in Journal of American Statistical Association, Biometrika, Journal of Royal Statistical Society Series C, Journal of Statistical Planning and Inference, and Statistics in Medicine. As a biomedical researcher, I have published as key author in New England Journal of Medicine, Proceedings of the National Academy of Science of the United States of America, Lancet, Blood, and AIDS among others.

- 1. **Hu Z**, Proschan M. "Two-part test of vaccine effect." **Statistics in Medicine**, 34: 1904-1911, 2015.
- Hu Z, Follmann DA and Miura K. "Vaccine design via nonnegative lasso-based variable selection." Statistics in Medicine, 34:1791-1798, 2015.
- 3. Zhang Z, Nie L, Soon G and **Hu Z**. "New methods for treatment effect calibration, with applications to non-inferiority trials." **Biometrics**, 72:20-29, 2016.
- 4. Crank M, Gordon I, Yamshchikov G, Sitar S, Hu Z, Enama M, Holman L, Bailer R, Pearce M, Koup R, Mascola J, Nabel G, Tumpey T, Schwartz R, Graham B, and Ledgerwood J. "Phase 1 Study of Pandemic H1 DNA Vaccine in Healthy Adults (Rapid Development and Production of a Pandemic H1 DNA Vaccine)." PLOS One, 10(4): e0123969, 2015.
- 5. Sarwar UN, Costner P, Enama ME, Berkowitz N, **Hu Z**, Hendel CS, Sitar S, Plummer S, Mulangu S, Bailer RT, Koup RA, Mascola JR, Nabel GJ, Sullivan NJ, Graham BS, Ledgerwood JE, and the VRC 206 Study Team. "DNA vaccines encoding Ebolavirus and Marburgvirus wild type glycoproteins are safe and immunogenic in a phase I clinical trial." **Journal of Infectious Diseases**, 211(4): 549–557.
- 6. **Hu Z**, Follmann DA and Wang N. "Effective balancing score for mean response estimation." **Biometrika**, 101: 613–624, 2014.

- 7. **Hu Z**, Qin J, and Follmann DA. "Semiparametric mixture survival model with application to MRFIT study." **Statistics and Its Interface**, 7: 19–26, 2014.
- 8. **Hu Z** and Follmann DA. "Acute-to-chronic ratio as a metric for HIV surveillance." **Open Journal of Statistics**, 4: 111–117, 2014.
- 9. Ledgerwood JE, DeZure A, Stanley DA, Novik L, Enama ME, Berkowitz N, Hu Z, Joshi G, Ploquin A, Sitar S, Gordon IJ, Plummer SA, Holman LA, Hendel CS, Yamshchikov G, Roman F, Nicosia A, Colloca S, Cortese R, Bailer RT, Schwartz RM, Roederer M, Mascola JR, Koup RA, Sullivan NJ, Graham BS, and the VRC 207 Study Team. "Safety and Immunogenicity of Chimpanzee Adenovirus Vector Ebola Vaccine: Preliminary Report." New England Journal of Medicine, DOI: 10.1056/NEJMoa1410863, 2014.
- 10. Chang LJ, Dowd KA, Mendoza FH, Saunders JG, Sitar S, Plummer SH, Yamshchikov G, Sarwar UN, Hu Z, Enama ME, Bailer RT, Koup RA, Schwartz RM, Akahata W, Nabel GJ, Mascola JR, Pierson TC, Graham BS, Ledgerwood JE, the VRC 311 Study Team. "Safety and tolerability of chikungunya virus-like particle vaccine in healthy adults: a phase 1 dose-escalation trial." Lancet, 384: 2046–2052, 2014.
- 11. Kibuuka H, Berkowitz NM, Millard M, Enama M, Tindikahwa A, Sekiziyivu A, Costner P, Sitar S, Glover D, Hu Z, Joshi G, Stanley D, Kunchai M, Bailer RT, Koup R, Nabel G, Mascola J, Sullivan N, Graham B, Michael N, Robb M. "Safety and immunogenicity of Ebola virus and Marburg virus glycoprotein DNA vaccines assessed separately and concomitantly in healthy Ugandan adults: a phase 1b, randomised, double-blind, placebo-controlled clinical trial." Lancet, 385:1545–1554, 2014.
- Swaminathan S, Hu Z, Rupert A, Chen Q, Stevens R, Rehm C, Metcalfe J, Baseler M, Lane C and Imamichi T. "Plasma Interleukin-27 (IL-27) levels are not modulated in patients with chronic HIV-1 infection." PLOS ONE, 9(6): e98989, 2014.
- 13. Saout C, Hasley R, Imamichi H, Tcheung L, **Hu Z**, Luckey M, Park J, Durum S, Smith M, Rupert A, Sneller M, Lane C and Catalfamo M. "Chronic exposure to type-I INF under lymphopenic conditions alters CD4 T cell homeostasis." **PLOS Pathogens**, 10(3): e1003976, 2014.
- 14. Ledgerwood J, Zephir K, Hu Z, Wei CJ, Chang LJ, Enama M, Hendel S, Sitar S, Bailer R, Koup R, Mascola J, Nabel G, Graham B and the VRC 310 Study Team. "Boost interval matters: a randomized phase I study to identify the minimum interval to observe the H5 DNA influenza vaccine priming effect." Journal of Infectious Disease, 208(3):418–422, 2013.
- 15. Miura K, Herrera R, Diouf A, Zhou H, Mu J, **Hu Z**, MacDonald N, Reiter K, Nguyen V, Shimp R, Singh K, Narum D, Long C and Miller L. "Overcoming allelic-specificity by immunization with 5-allelic forms of Plasmodium falciparum Apical Membrane Antigen 1." **Infection and Immunity**, 81(5):1491–1501, 2013.
- 16. Hasley R, Hong C, Li W, Friesen T, Wilhelm C, Nakamura Y, Kim G, Park J, Hixon J, Durum S, Hu Z, Sneller M, Imamichi T, Oguariri R, Lane CH and Catalfamo M. "HIV immune activation drives increased expression of Eomesodermin in memory CD8 T cells in association with transcriptional downregulation of CD127." AIDS, 27(12):1867–1877, 2013.
- 17. Hurley A, Smith M, Karpova T, Hasley RB, Belkina N, Shaw S, Balenga N, Druey KM, Nickel E, Packard B, Imamichi H, **Hu Z**, Follmann DA, McNally J, Higgins J, Sneller M, Lane CH and Catalfamo M. "Enhanced effector function of CD8 T

- cells from healthy controls and HIV infected patients occurs through thrombin activation of the Protease-activated receptor-1." The Journal of Infectious Disease, 207(4): 638-650, 2013.
- 18. **Hu Z**, Follmann DA and Qin J "Semiparametric double balancing score estimation for incomplete data with ignorable missingness." **Journal of American Statistical Association**, 107: 247–257, 2012.
- 19. Ledgerwood JE, Hu Z, Gordon IJ, Yamshchikov G, Enama ME, Plummer S, Bailer R, Tumpey TM, Koup RA, Mascola JR, Nabel GJ, Graham BS and the VRC 304 and VRC 305 Study Teams. "H5 DNA Influenza Vaccination is Immunogenic by Intradermaland Intramuscular Routes in Humans." Clinical and Vaccine Immunology, 19:1792–1797.
- 20. Enama ME, **Hu Z**, Gordon I, Costner P, Ledgerwood JE, Grady C. "Comparison of standard and simplified consent forms in investigational influenza vaccine clinical trials." **Contemporary Clinical Trials**, 33: 895–902, 2012.
- Osinusi A, Naggie S, Poonia S, Trippler M, Hu Z, Schlaak JF, Fishbein D, Masur H, Polis MA, Kottilil S. "ITPA gene polymorphisms significantly affect hemoglobin decline and treatment outcomes in HIV/HCV co-infected patients." Journal of Medical Virology, 84: 1106-1114, 2012.
- Sneller MC, Hu Z and Langford CA. "A Randomized Controlled Trial of Rituximab Following Failure of Antiviral Therapy for Hepatitis C-Associated Cryoglobulinemic." Arthritis & Rheumatism, 64: 835–842, 2012.
- Hu Z, Follmann DA, and Qin J "Dimension reduced kernel estimation for distribution function with incomplete data." Journal of Statistical Planning and Inference, 141: 3084–3093, 2011.
- 24. Ledgerwood JE, Wei CJ, Hu Z, Gordon IJ, Enama ME, Hendel CS, McTamney PM, Yassine H, Bailer R, Tumpey TM. Koup RA, Mascola JR, Nabel GJ, Graham BS1 and the VRC 306 Study Team (2011). "DNA priming improves influenza vaccine immunogenicity in humans." Lancet, 11:912–924, 2011.
- 25. Hodge JN, Srinivasula S, Hu Z, Read SW, Porter BO, Mican J, Paik C, Di Mascio M and Sereti I. "Decreases in IL-7 levels during ART suggest a primary mechanism of receptor-mediated clearance with IL-7 levels normalizing despite persistent CD4 lymphopenia." Blood, 118:3244–3253, 2011.
- 26. Matthews GV, Manzini P, Hu Z, Khabo P, Maja P, Mutchaba G, Sangweni P, Metcalf J, Pool N, Orsega S, Emery S on behalf of the PHIDISA II study team. "Impact of 3TC on HIV and HBV related outcomes in HIV/HBV individuals in a randomized clinical trial of antiretroviral therapy in South Africa." AIDS, 14:1727–1735, 2011.
- 27. Dlamini J, Hu Z, Morris L, Somaroo H, Ledwaba J, Maldarelli F, Highbarger H, Sangweni P, Follman D, Dewar R, Pau A, and the Phidisa Study Group. "Genotypic Resistance at Viral Rebound among Patients Who Received Lopinavir/ritonaviror Efavirenz-Based First Antiretroviral Therapy in South Africa." Journal of Acquired immune Deficiency Syndrome, 58:304–308, 2011.
- 28. Dlamini J, **Hu Z**, Somaroo H, Highbarger H, Sangweni P, Follman D, Dewar R, Pau A. "Lack of effect from a previous single dose of Nevirapine on virologic and immunologic responses after 6 months of antivetroviral regimens containing efavirenz or lopinavir-ritonavir." **Pharmacotherapy**, 31: 158–163, 2011.

- 29. **Hu Z**, Follmann DA, and Qin J "Semiparametric dimension reduction estimation for mean response with missingness." **Biometrika**, 97: 301–319, 2010.
- 30. Ledgerwood JE, Costner P, Desai N, Holman L, Enama ME, Yamshchikov G, Mulangu S, Hu Z, Andrews CA, Sheets RA, Koup RA, Roederer M, Bailer R, Mascola JR, Pau MG, Sullivan NJ, Goudsmit J, Nabel GJ, Graham BS and the VRC 205 Study Team. "A Replication Defective Recombinant Ad5 Vaccine Expressing Ebola Virus GP Is Safe and Immunogenic in Healthy Adults." Vaccine, 29: 304-313, 2010.
- Brittain E and Hu Z "Non-inferiority trial design and analysis with an ordered three-level categorical endpoint." Journal of Biopharmaceutical Statistics, 19: 685–699, 2009.
- 32. Komarow H, **Hu Z**, Brittain E, Uzzaman A, Gaskins D, Metcalfe DD. "Serum tryptase levels in atopic and non-atopic children." **Journal of Allergy and Clinical Immunology**, 124: 845–848, 2009.
- 33. Hill VL, Simpson VZ, Higgins J, **Hu Z**, Stevens RA, Metcalf JA and Baseler M. "Evaluation of the Performance of the Sysmex XT-2000i Hematology Analyzer with Whole Bloods Stored at Room Temperature." **Lab Medicine**, 40: 709–718, 2009.
- 34. **Hu Z**, Qin J, and Follmann DA "Semiparametric two-sample change-point model." **Journal of Royal Statistical Society Series C**, 57: 589–607, 2008.
- 35. **Hu Z** and Wang, N. "Semiparametric mixed-effects model with latent covariate in Colon carcinogenesis study." **Statistics and Its Interface**, 1: 75–86, 2008.
- 36. **Hu Z**, Qin J, Follmann DA, and Dewar, R. "Nonparametric likelihood approach for assessing the accordance between two measurements and its application to viral load determination with limit of detection." **Statistics in Medicine**, 27: 4489–4501, 2008.
- 37. Catalfamo M, Di Mascio M, **Hu Z**, Srinivasula S, Thaker V, Adelsberger J, Rupert A, Baseler M, Tagaya Y, Roby G, Rehm C, Follmann D and Lane C. "HIV infection associated immune activation occurs by two distinct pathways that differentially affect CD4 and CD8 T cells." **Proceedings of the National Academy of Sciences of the United States of America**, 105: 19851–19856, 2008.
- Suzman DL, McLaughlin M, Hu Z, Kleiner DE, Wood B, Vailati M, Lempicki RA, Mican JM, Suffredini A, Masur F, Polis MA and Kottilil S. "Identification of novel markers for liver fibrosis in HIV/HCV co-infected individuals using genomicsbased approach." AIDS, 22: 1433–1439, 2008.
- 39. **Hu Z** and Follmann DA "Statistical methods for active extension trials." **Statistics** in Medicine, 26:2433–2448, 2007.
- 40. Highbarger HC, **Hu Z**, Kottilil S, Metcalf JA, Polis MA, Vasudevachari MB, Lane CH and Dewar R. "Comparison of the Abbott 7000 and Bayer 340 systems for measurement of Hepatitis C viral load." **Journal of Clinical Microbiology**, 45: 2808–2812, 2007.
- 41. Pau AK, McLaughlin M, **Hu Z**, Polis MA, Kottilil S. "Predictors for Hematopoietic Growth Factors Use in HIV/HCV Co-Infected Patients Treated with Peginterferon alfa 2b and Ribavirin." **AIDS Patient Care and STDs**, 9: 612–619, 2006.

- 42. Wu L, Kottilil S, Lempicki R, Yang J, McLaughlin M, **Hu Z**, Koratich C, Rehm C, Masur H, Kleiner DE, Polis MA. "Hepatic histologic response (HR) to combination therapy among HCV/HIV coinfected individuals: Interferon-induces HR independent of Sustained Virologic Response (SVR)." **AIDS Research and Human Retroviruses**, 22:1091–1098, 2006.
- 43. **Hu Z**, Wang N and Carroll RJ. "Profile-Kernel versus backfitting in the partially linear models for longitudinal/clustered data." **Biometrika**, 91:251–262, 2004.
- 44. Cohen N, **Hu Z**, Stanley, SD and Wang N. "Comparison of serum and urinary concentration of clenbuterol with and without concomitant administration of furosemide in horses." **Veterinary Therapy**, 3: 316–325, 2002.
- 45. Nelson P and **Hu Z**. "Consistency of the Synchronized Traffic Flow of Kerner with a Diffusively Corrected Lighthill? Whitham Model." **Proceedings of Traffic and Transportation Studies 2000**, 594–601.

Invited Presentations

The 4th IMS Asia Pacific Rim Meeting, Hong Kong June 2016 NIAID workshop - Infectious Diseases Research: Quantitative Methods and Models in the Era of Big Data, Bethesda, MD November 2015 Office of Biostatistics Research, National Heart, Lung and Blood Institute, Bethesda, MDNovember 2014 The 3rd IMS Asia Pacific Rim Meeting, Taipei, Taiwan June 2014 Department of Biostatistics, Johns Hopkins University, Baltimore, MD April 2014 Department of Biostatistics, Georgetown University, DC, November 2013 Department of Statistics, University of Michigan, Ann Arbor, MI September 2011 International Chinese Statistical Association, New York, NY June 2011 Department of Statistics, George Mason University, VA December 2009 Department of Mathematical Sciences, Portland State University, Portland, OR April 2008 Biostatistics Research Branch, National Institute of Allergy and Infectious Diseases. Bethesda, MD June 2004 International Chinese Statistical Association, San Diego, CA June 2004 CDRH, Food and Drug Administration, Rockville, MD September 2003

Awards

NIH Employee Awards

NIH Director's award 2015 Special Act/Service Award 2005, 2006, 2008, 2011, 2012, 2015 Performance Award 2007, 2009

Student Awards

Student paper award and travel fellowship. The International Chinese Statistician Association (ICSA), June 2004
Student paper award and travel fellowship. The Western North American Region of The International Biometric Society (WNAR), June 2003
Authorized University Tuition Fellowship (AUTF). Texas A &M University, 2003–2004
Authorized University Tuition Fellowship (AUTF). Texas A &M University, 2000–2001

SCIENTIFIC REVIEW

- Clinical Scientific Review Committee, National Institute of Allergy and Infectious Diseases.
- Preventative Scientific Review Committee, National Institute of Allergy and Infectious Diseases.

• Referee for Journal of American Statistical Association, Biometrics, Statistica Sinica, Statistics in Medicine, Journal of Statistical Planning and Inference, Statistics and Its Interface, Statistical Computation and Graphics, Canadian Journal of Statistics, Communications in Statistics-Theory and Methods, Scandinavian Journal of Statistics, TEST, Annals of Internal Medicine.